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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,707	02/26/2002	Gregory G. Brucker	1001.2256101	1518

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EXAMINER	
TYSON, MELANIE RUANO	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
10/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/083,707	BRUCKER ET AL.	
	Examiner	Art Unit	
	MELANIE TYSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19,39,40,42-58,60,61 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,19,39,40,42-58,60,61, and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This action is in response to the applicant's amendment received 22 July 2009. Claims 1-16, 18, 20-38, 41, 59, and 62 are cancelled. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17, 19, 39, 40, 42-56, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al. (U.S. Patent No. 6,325,826), Marotta et al. (U.S. Patent No. 6,261,305 B1), and Crocker et al. (U.S. Patent No. 5,843,116). Vardi discloses a system (see entire document) comprising balloon catheters and a bifurcated stent including a stent body (40) and a plurality of movable members (38) engaged to

the stent wall, retained substantially within the plane of the stent wall, and expandable radially outward from the stent wall to form a scaffold. Vardi further discloses the movable members and stent body may be balloon expandable or self-expandable, (for example, see column 9, lines 33-35). Vardi fails to disclose the system comprises only a single balloon catheter having a single balloon and a bulge portion for expanding the bifurcated stent.

Marotta discloses a catheter system (see entire document) comprising a catheter having a balloon arrangement. Marotta teaches a bulge portion positioned within the circumferential plane of a body region of the endoprosthesis prior to expansion (for example, see Figure 1) that extends radially through a side opening of the endoprosthesis outside the circumferential plane after expansion, thus is considered "predetermined," and extending less than the entire circumference of the body region of the balloon (for example, see Figure 4) in order to push a movable member radially outward. The substitution of one known element (a single catheter having a single balloon with a body region and a bulge region) for another (two balloon catheters as shown in Vardi) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the balloon catheter in Vardi would have yielded predictable results, namely, a simplified deployment system to deploy the bifurcated stent having movable members. Vardi and Marotta fail to disclose the bulge region has a different pressure and/or inflation characteristics than the elongated body region.

Crocker discloses a system (see entire document) comprising a catheter having a balloon (for example, see Figures 1-3). Crocker teaches a bulge region (30) being

located between a proximal end and a distal end, wherein the bulge is positioned at a predetermined circumferential location (for example, see column 1, lines 10-15). Crocker further teaches the expansion characteristics can be achieved by modifying the expansion properties of the balloon itself, including providing zones of differing wall thickness (for example, see column 5, lines 40-45). Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Crocker to the balloon of Vardi and Marotta would have yielded predicable results and resulted in an improved system, namely, a system that would provide the balloon of Vardi and Marotta a higher expansive energy only where needed, such as along the center where the movable members lie across the bifurcation point, thus minimizing the risk of damaging surrounding healthy tissue.

Claims 57, 58, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al. in view of Marotta et al. Vardi discloses the claimed invention (see rejection above for similar limitations) including an alternate embodiment in which the entire stent may be made of self-expandable material (for example, see column 9, lines 33-35), in which expansion of the stent wall would simultaneously cause the movable members to expand. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the bifurcation stent of self-expanding, or shape memory, material as described in the alternate embodiment, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design

choice. See rejection above for other similar limitations recited in the claims. Vardi fails to disclose a bulge region as claimed.

Marotta discloses a catheter system (see entire document) comprising a catheter having a balloon arrangement. Marotta teaches a bulge portion positioned within the circumferential plane of a body region of the endoprosthesis prior to expansion (for example, see Figure 1) that extends radially through a side opening of the endoprosthesis outside the circumferential plane after expansion, thus is considered "predetermined," and extending less than the entire circumference of the body region of the balloon (for example, see Figure 4) in order to further push a movable member radially outward (for example, see column 5, lines 14-16 and 25-27). The substitution of one known element (a single catheter having a single balloon with a body region and a bulge region) for another (two balloon catheters as shown in Vardi) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the balloon catheter in Vardi would have yielded predictable results, namely, a simplified deployment system to deploy the bifurcated stent having movable members that would aid in expanding the movable members.

Response to Arguments

Applicant's arguments filed 22 July 2009 have been fully considered but they are not persuasive. The applicant argues that Vardi, Marotta, and Crocker fail to disclose or suggest a "predetermined" bulge region at a "predetermined" location around a circumference of the body region. However, Marotta teaches a bulge region located between the proximal and distal end of the balloon (for example, see Figure 4). The

bulge region is considered "predetermined" and located at a "predetermined" location around a circumference of the body region in that it is predetermined the bulge region occurs at the location of the movable member. Therefore, it is the examiner's position that Marotta discloses the limitations as recited in the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
October 14, 2009

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773